SECTION 1 – GENERAL DESCRIPTION
510(k) Notification Information Collection

K051749

Sponsor
Endoscopic Technologies, Inc.; d/b/a Estech

Person Responsible for File
Art Bertolero
Chief Executive Officer
Estech Technologies

Device Trade Name
Estech Cobra Surgical System™
Accessories presented in this premarket notification:
Estech Cobra Adhere XL Surgical System
Estech Cobra Surgical Probe
Estech Cobra Bipolar Recording Electrode

Common Name
Electrosurgical Probes and accessories

Classification Name
Class II, Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400);

Product Code
GEI

Establishment Registration Number
2953686

Address of Manufacturing Facility and Sterilization Site:

Manufacturing Facility	Sterilization Site
4135 Blackhawk Plaza Circle Suite 150 Danville, CA 94506 Tel: 925-648-3500 Contact: Art Bertolero Establishment Registration: 2953686	Sterigenics 5725 W. Harold Gatty Dr. Salt Lake City, UT 84116 Tel: 801-328-9901 Fax: 801-328-9002 Establishment Registration: 1721676

SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Information:

Category	Comments
Sponsor:	Estech 4135 Blackhawk Plaza Circle . Suite 150 Danville, CA 94506 Tel: 925-648-3500
Correspondent:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501
Contact Information:	Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Electrosurgical Probe
Device Proprietary Name:	Estech Cobra Surgical System™
Device Classification:	21 CFR 878.4400

Predicate Device Information:

Predicate Devices:	Electrosurgical Probe (K981981) Cobra Adhere Surgical System (K041599) Detect Mapping and Pacing Tool (K040812)
Predicate Device Manufacturers:	Boston Scientific Corporation Endoscopic Technologies Medtronic
Predicate Device Common Name:	Electrosurgical Probe
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification Number:	Class II

b. Date Summary Prepared
July 22, 2005

c. Description of Device
The Estech Cobra Surgical System is a family of devices including RF Ablation Probes, with either a malleable or flexible shafts, used in conjunction with the Cobra Electrosurgical Unit (ESU) and other accessories, including the Estech Cobra Bipolar Recording Electrode. The System is intended for use by surgeons for the coagulation of cardiac and soft tissues during open surgical procedures.

d. Intended Use
The intended use for the Estech Cobra Surgical System is as follows:
The Estech Cobra Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during

general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

e. Comparison to Predicate Device

The **XL** version of the Estech Cobra Surgical System is substantially equivalent in intended use, technology, design and materials to the predicate device. The XL version has up to seventeen electrodes on the ablation probe. The original premarket notification device had an upper limit of seven electrodes. The Stabilizers differ in size and handle configuration. The XL version has an Introducer to facilitate the placement of the System.

The Estech Cobra Surgical Probe is substantially equivalent in intended use, technology, design and materials to the predicate system. The Cobra Surgical Probe does not have the capability for a cooling stream of water to be run through the shaft and it does not interface with a Stabilizer. This version of the Cobra Surgical Probe is identical to the Boston Scientific Electrosurgical Probe.

The Estech Cobra Bipolar Recording Electrode is substantially equivalent to the surgical intended use, sensing and pacing characteristics of the predicate device. Both are hand-held devices that are intended to be used only in an open surgical field. They are not implantable.

f. Summary of Supporting Data

No biocompatibility data is necessary since the materials in the modified ablation probes (XL and Surgical Probe) are identical to those described in the predicate 510(k)s. The materials of the Recording Electrode are identical to those in the ablation probes.

Preclinical performance data is supplied to demonstrate that the XL version of the cooled Estech Cobra Adhere Ablation Probe met the same pertinent specifications as the predicate version.

No performance data is necessary for the Estech Cobra Surgical Probe since it is identical in design, materials and manufacture to the predicate device.

Preclinical performance data is supplied to demonstrate that the Estech Cobra Bipolar Recording Electrode operates as intended.

Additionally, Estech certifies that the accessories are in compliance with the pertinent sections of the FDA consensus standard, *AAMI / ANSI HF-18: Electrosurgical devices.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2005

Estech, Inc.
c/o Mr. Craig Coombs
Coombs Medical Device Consulting
1193 Sherman Street
Alameda, California 94501

Re: K051749
Trade/Device Name: Estech Cobra Surgical System™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 27, 2005
Received: July 7, 2005

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bruehl for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051749

Device Name: Estech Cobra Surgical System™

Indications For Use:

The Estech Cobra Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use __X__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051749